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Future of the Animal Health Industry



by David A. Phillipson, D.V.M.*

The following is an excerpt of remarks given by Dr. Phillipson on December 6, 1977, and sponsored by the Gamma Chapter of Phi Zeta.

The future of the animal health industry is uncertain. There is a web of unrelenting governmental regulation, leaving little room for optimism in our outlook. No reasonable person is in principle opposed to some governmental regulation, but reasonable people expect reasonable, responsible regulation—not a proliferation of confusing, often contradictory dictates that threaten to paralyze and transform our society.

For years, the federal government had a major regulatory responsibility in only four areas: antitrust, financial institutions, transportation, and communications. Today, however, there are 83 federal agencies engaged in regulating some aspect of private activity. It has been estimated that today federal, state, and local officials enact some 150,000 new laws annually, and each new law requires an average of 10 accompanying regulations.

*Dr. Phillipson is Vice President and General Manager of The Upjohn Company, Kalamazoo, MI. He also is President of the Animal Health Institute, an organization of 59 commercial producers of veterinary pharmaceuticals and biologics. The Animal Health Institute, which originated in 1941 in Des Moines as the Animal Serums and Vaccines Association, is now based in Washington, D.C.

The animal health industry is regulated by three principal agencies: FDA, EPA, and USDA. What has been their impact? In 1957, it took about one year and \$100,000 to clear a major new food animal product. In 1967, two to three years and nearly \$1 million were needed. Today, a clearance period of five to seven years and \$3 million are typical.

The major impact of regulation has been largely economic. Unfortunately, economic considerations have been generally ignored in governmental decision-making. For example, the FDA's "sensitivity-of-methods" regulations are so complicated and costly that they may result in the removal of several vitally important products from the market, in a delay in the approval process, and in an escalation of costs of research and development. The "combination drug" policy packs a similar economic wallop. Other regulations having an economic impact are the Delaney amendment, the antibiotics-in-feed issue, good laboratory practices, good manufacturing practices, and just normal bureaucratic redtape.

Even without a crystal ball, it is possible to foresee some of the economic consequences of over-regulation. There will be a slower output of new products, each of which will cost more. Some products already approved may be removed from the market. The veterinarian and livestock and poultry producers will have less choice of increasingly more costly products. Moreover, some of the smaller companies will further limit research and development. Even DuPont has dropped 90% of "new ventures" research. Smaller companies will consolidate in order to survive to meet the complex, time-consuming, costly demands of overregulation.

The dramatic shift from a basically rural America to an urbanized society is reflected in the make-up of our law-making bodies. Only 110 of the 435 U.S. Representatives represent districts where more than 20% of the voters are engaged in agriculture. Only 123 districts have a dairy operation. These examples show how far removed from the food production process are most of our congressmen.

Justice Brandeis said, "If we would guide by the light of reason, we must let our minds be bold." That, I think, is a message that must be conveyed to our regulators, legislators, and the public.